NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

PND7
IMPACT OF COPAYMENT REDUCTION OR EXEMPTION PROGRAMME ON GENERIC DRUG UTILISATION: THE SPECIFIED DISEASE TREATMENT RESEARCH PROGRAMME IN JAPAN

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OBJECTIVES: In Japan, the Specified Disease Treatment Research Programme provides copayment reduction or exemption for patients with 56 designated rare and intractable diseases/syndromes according to disease severity and patients' income levels. The objective of this study is to examine the impact of the Specified Disease Treatment Research Programme on generic drug utilisation under the fee-for-service payment system. **METHODS:** We extracted and analysed claims data with indication for Parkinson's disease, which is subject to the Specified Disease Treatment Research Programme, from the Social Health Insurance claims data processed from February to April 2011. Extracted data were analysed in terms of patients' age and income levels, types of public subsidy, prescribed places (clinic/hospital or pharmacy) and pharmacologic classes. **RESULTS:** During the three months, cumulative total number of 72,145 patients in Social Health Insurance programme were prescribed drugs for Parkinson's disease, of which 10,013 were entitled to the Specified Disease Treatment Research Programme. Overall average generic utilisation rate is 15.46% on a volume basis. Average generic utilisation rate for those entitled to the Specified Disease Treatment Research Programme is 4.04%, whilst for patients eligible for medical assistance programme is 21.75%. Generic utilisation is fewer in the elderly than in the younger generation. **CONCLUSIONS:** Our study finds low generic utilization rate for patients with Parkinson's disease entitled to the Specified Disease Treatment Research Programme. This might be suggesting that without mandatory clinical guidelines nor guidance for generic substitution, the Specified Disease Treatment Research Programme has been promoted branded prescribing under the fee-for-service system. Additional studies with other designated rare and intractable diseases/syndromes are expected to generalise the study result.

PND8
ACETYL-L-CARNITINE FOR THE TREATMENT OF PERIPHERAL NEUROPATHIC PAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Acetyl-L-carnitine (ALC), as a constructive component in fatty acid metabolism, is considered a potential agent for peripheral neuropathic pain (PNP). We aimed to access the efficacy and safety of ALC for the treatment of patients with PNP. **METHODS:** We searched PubMed up to March 2014 for randomized controlled trials (RCTs) comparing ALC with placebo or other active medications in diabetic and non-diabetic PNP patients. Two reviewers independently screened for eligible studies, assessed risk of bias, and extracted data. Mean difference (MD) and 95% confidence interval (CI) were used for pooling continuous data. **RESULTS:** Four RCTs compared ALC with placebo and reported in 3 articles (n = 523) were included. Compared with placebo, ALC significantly reduced Visual Analogue Scale (VAS) of PNP patients (MD, 1.28; 95%CI, 0.93-1.64, $P < 0.00001$). In the subgroup analysis, the efficacy of ALC on VAS was similar in different administration route (intramuscular-oral sequential subgroup: MD, 1.19; 95% CI, 0.34-2.04, $P = 0.006$; oral only subgroup: pooled MD, 1.15; 95% CI, 0.33-1.96, $P = 0.006$), and ALC appeared more effective in diabetic PNP patients than non-diabetic PNP patients (diabetic subgroup: MD, 1.47; 95% CI, 1.06-1.87, $P < 0.00001$; non-diabetic subgroup: MD, 0.71; 95% CI, -0.01-1.43, $P = 0.05$). No severe adverse events related to ALC were reported. The common adverse events were pain, headache, paraesthesia, hyperesthesia, retching, biliary colic and gastrointestinal disorders. The rates of total adverse events were similar in ALC and control group. **CONCLUSIONS:** ALC could reduce VAS in PNP patients with acceptable safety. However, further trials with larger population and longer follow-up are required to confirm these findings.

PND9
AGE AND GENDER DISTRIBUTION OF OUTPATIENT CARE PHYSIOTHERAPY SERVICES FOR CEREBRAL PALSY AND OTHER PARALYTIC SYNDROMES IN HUNGARY

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OBJECTIVES: The aim of our study is to assess the utilization of out-patient care physiotherapy services related to cerebral palsy and other paralytic syndromes according to age and gender. **METHODS:** The data come from the financial data base of the National Health Insurance Fund Administration involving the year of 2009. The activity list was provided by the rulebook on the application of the activity code list in out-patient care. The Cerebral Palsy and other paralytic syndromes are listed in the International Classification of Diseases (ICD) with code of G80-G83. The number of cases in physiotherapy activities were determined per 10000 persons by age and gender in outpatient care, 2009. **RESULTS:** Diseases of the nervous system account for 1331675 cases in the annual number of the physiotherapy-related activities (32318413 cases) showing an approximately 4.12% prevalence. The prevalence of the Cerebral Palsy and other paralytic syndromes were 31.56% in the group of of diseases of the nervous system. The average number of cases of physiotherapy activities per 10000 persons accounted for 433 cases in 2009. The average number of cases per 10000 persons for males and females were 508 cases for males and 364 cases for females. The high number of physiotherapy treatment is provided for both gender in the youngest age group and 60-74 age groups in male and 70-84 age groups in female. **CONCLUSIONS:** The cerebral palsy and other paralytic syndromes at the diseases of the nervous system show high prevalence, indicating the importance of prevention.

PND10
ASSESSMENT OF OUTPATIENT PHYSIOTHERAPY SERVICES IN DISEASES OF THE NERVOUS SYSTEM IN HUNGARY

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OBJECTIVES: The purpose of our study is to assess the frequency related to Diseases of the nervous system within out-patient care and determine the total health care expenses of them in Hungary in 2009. METHODS: CONCLUSIONS: **METHODS:** Data were derived from the nationwidewide database of Hungarian National Health Insurance Fund Administration (NHIFA), based on official reports of outpatient care institutes. The 151 different types of treatment codes are listed in the chapter of the Guidelines of NHIFA for `Physiotherapists, massage-therapists, conductors and other physiotherapy practices`. The diseases of the nervous system are listed in the International Classification of Diseases (ICD) with code of G00-G99. **RESULTS:** Diseases of the nervous system account for 1.331.675 cases in the annual number of the physiotherapy-related activities (32318413 cases) showing an approximately 4,12% prevalence. The following top-10 medical procedure were responsible for 48.48% (645562) of total activities: individual training (7.79 %), passive motion therapy on multiple limbs (6.24%),selective nerve stimulation therapy (5.89%), muscle strengthening exercise (5.82%), training for circulation improvement (4.6%), parts of the body per individual physiotherapy (4.19%), ergotherapy (3.78%), exercise to prevention of cardiovascular complications (3.68%), Hand massage (3.53%), electrotherapy - facial nerve (2.96%). The total financial cost of all of the physiotherapeutic treatments provided in diseases of the nervous system was 388 million Hungarian Forint (1.25 million Euro) health insurance subsidy in 2009. **CONCLUSIONS:** The 20 most frequent treatments accounts for 71.72 % (955073) of total services. The passive procedures are more common than the active in the 20 most commonly used activities list. Our results could be extremely useful for economic evaluation of the health care system and in the financial planning of the treatments of the studied diseases of the nervous system.

PND11
REVERSAL OF CHRONIC FATIGUE INDUCED ALTERATIONS BY SESAMOL IN MICE: EVIDENCE FOR INVOLVEMENT OF OXIDATIVE STRESS AND INFLAMMATORY PATHWAY

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OBJECTIVES: A wide body of literature suggest *in vivo* neuroprotective, antioxidant, anti-inflammatory and anti-ageing properties of Sesamol. This study was aimed to elucidate the protective effect of sesamol in experimental model of chronic fatigue syndrome (CFS). **METHODS:** Firstly, Sesamol was tested for its antidepressant potential in mouse models using forced swim test (FST) and tail suspension test (TST). Later, Sesamol was examined in mouse model of chronic stress fatigue induced by chronic forced swimming for 15 days. Brain biochemical [superoxide dismutase (SOD), glutathione-S-transferase (GST), glutathione (GSH), lipid peroxidation and nitrite levels) and plasma cytokines [tumour necrosis factor α (TNF-α) and interleukin 6 (IL-6)] levels were assessed to correlate the possible mechanism of action associated with fatigue symptoms. Further, adrenal ascorbic acid measurement was done to correlate corticosterone levels. **RESULTS:** Mice administered with sesamol showed significant decrease in immobility time in acute FST and TST. Sesamol significantly attenuated progression of CFS in experimental model as compared to control. Sesamol also corrected the other cognitive deficits (locomotor activity, motor activity, memory retention, hyperalgesia) associated with CFS. Furthermore, it rectified the diminished levels of antioxidant enzymes such as SOD, GST and GSH in brain and altered levels of proinflammatory cytokines (TNF-α and IL-6). **CONCLUSIONS:** This finding suggests that anti-fatigue activity of sesamol against chronic induced fatigue in mice. The present outcome offers a therapeutic application of sesamol against CFS and also offers the scope for its development against neuropsychiatric disorders.

URINARY/KIDNEY DISORDERS – Clinical Outcomes Studies

PUK1
TADALAFIL IN BENIGN PROSTATIC HYPERPLASIA: PROTOCOL FOR THE SYSTEMATIC REVIEW OF ADVERSE EVENTS

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OBJECTIVES: Benign prostatic hyperplasia (BPH) is an age related disorder, however its symptoms begin to appear in some men as early as age 40 years. As per estimates every second person has BPH by the age of 60 and 90% of individuals develop BPH by 85 years. Tadalafil is a selective PDE5 enzyme inhibitor approved to treat men with BPH. The aim is to systematically review the medical literature for randomized control trial and identify the adverse events (AE) associated with tadalafil use in BPH. **METHODS:** All published randomized controlled trials (RCTs) comparing tadalafil with a placebo or active interventions for the treatment of BPH with or without any co-morbidity (such as but not limited to erectile dysfunction) were sought from PubMed, EMBASE, Cochrane Library, and Google Scholar. Abstracts, titles and then the full-text manuscripts of all selected articles will be retrieved and assessed by two independent reviewers against the eligibility criteria. Disagreements over study inclusion will be resolved through discussion. A pre-designed data extraction form will be used by two reviewers for the extraction of AE and other study findings. Cochrane risk of bias assessment checklist will be used for the risk of bias assessment. An Excel spreadsheet will be used to extract data from the selected articles. Descriptive and quantitative data synthesis will be done for AE reported in all the studies. Meta-analysis will be performed using RevMan (v5.0). **RESULTS:** Though there are several studies assessing tadalafil use in erectile dysfunction, a systematic review/meta-analysis of the evidence reporting its AE profile when used for